

BROOKHAVEN NATIONAL LABORATORY GENERAL CLINICAL RESEARCH CENTER POLICY SUBJECT: Bloodborne Pathogens Exposure Control Plan	GCRC POLICY: IC-06.01	PAGE 1 OF 7
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INTRODUCTION

This plan has been developed in order to comply with the OSHA rule 29 CFR 1910.1030 entitled Occupational Exposure to bloodborne pathogens.

Infection with HIV, hepatitis B, C and other bloodborne pathogens including those found in the blood, organs, or other tissues from experimental animals infected with HIV or HBV(including primate blood) can occur in both subjects and health care workers. Infection with these pathogens cannot be predicted by superficial inspection of either subject or health care worker and knowledge of this information cannot be mandated. Therefore, the policy of the Medical Department is to assume that all blood and other body fluids from all subjects are potentially infectious. This plan is intended to limit occupational exposure to bloodborne pathogens. It is based on CDC guidelines and OSHA regulations and is available to all health care workers in this Department. It is kept in the Medical Department's Infection Control Manual on the SBMS database.

Infection Control and the CRC Manager, shall review the plan at least annually and the Department Chair to reflect modified tasks and procedures, and revised employee positions with occupational exposure.

Other information related to this plan is available in the following documents:

1. OSHA Final Rule 29 CFR Part 1910.1030
2. Bloodborne Pathogens Training documentation
2. Animal Studies at Clinical Facilities IC-13

Each employee is expected to comply with the provisions of the Exposure Control Plan. It is, however, the responsibility of Principal Investigators of Research Programs and Laboratory Supervisors to ensure full compliance.

All full and part-time employees shall comply with all requirements of this document if they are Category I (see Exposure Determination, below). Students and on-site collaborators who will be in Category I shall have Bloodborne Pathogen Training. On-site collaborators in Category I shall produce evidence of hepatitis immunization or declination from their home institution. The Quality Assurance, Care and Safety Committee has determined that students in Category I shall be apprised of the requirement for hepatitis immunization by their Sponsor and advised to obtain and be prepared to document two of three required injections prior to beginning work or sign the declination. The final injection may be obtained at the Occupational Medicine Clinic. (See OMC's Bloodborne Hazards (BBH) and Healthcare Provider (HCP) protocols.

DEFINITIONS

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV) also primate blood.

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry, which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or items to the point where they are no longer capable of transmitting infectious particles, and the surface or item is rendered safe for handling, use, or disposal.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazards from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of the employee's duties.

Handwashing Facilities means a facility providing an adequate supply of potable water, soap and single use towels or hot air drying machines.

HBV means hepatitis B virus.

HCV means hepatitis C virus.

HIV means human immunodeficiency virus. Can be found both in humans and primates.

B-virus is a virus carried by primates

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Needleless systems means a device that does not use needles for:

1. The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
2. The administration of medication or fluids; or
3. Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means

1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visible contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
3. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV –containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV, HBV or B-virus.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic subjects; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Standard Precautions is an approach to infection control. According to this concept (1) blood; (2) all body fluids, secretions except sweat, regardless of whether or not they contain visible blood; (3) nonintact skin; and (4) mucous membranes of ALL subjects considered infectious for HIV, HBV and other bloodborne pathogens. Developed by the CDC and used during the care of all subjects whether or not they are known to have an infection. .

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is another approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

EXPOSURE DETERMINATION

All employees with a potential occupational hazard of exposure to blood or other infectious body fluids shall be required to undergo training according to this Exposure Control Plan.

The following list of tasks with risk of exposure to bloodborne pathogens includes, but is not limited to:

Category I

a. Task requires exposure to blood or potentially infectious body fluids:

- Phlebotomy
- Insertion of intravenous catheter, contrast material or medication
- Dressing change of wounds
- Performing any laboratory procedure requiring processing of blood, body fluids or tissue
- Cleaning up any blood or body fluid spills
- Changing the bed or stretcher that has become contaminated with blood or body fluids, excluding urine, or non-bloody feces
- Removal or manipulation of intravenous or arterial catheters.

b. Task does not normally involve exposure to blood or potentially infectious body fluid or tissue, but may require performing unplanned Category I a. tasks:

- Disinfection, sterilization, or cleaning equipment involved in subject care or invasive procedures requiring phlebotomy

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Transporting patients within the CRC
Transporting laboratory specimens which have been properly packaged for transport
Routine cleaning of General Clinical Research Center (GCRC) or Medical Department areas and laboratories

Category II

Task where exposure is highly unlikely, but not impossible:

- Secretarial duties
- Clerical duties not based in a subject care area
- All tasks related to the handling of medical records

Exposure Determination List

The following job descriptions (Job Training Assessments "JTA") are defined in the Medical Department's Training Plan and require Bloodborne Pathogen Training:

1. Laboratory /Research Position - Bloodborne Pathogen Qualified.
2. Physician Medical Laboratory/Clinical Researcher
3. Physician/Researcher - Dispersible Radionuclide Qualified
4. Nurse
5. Clinical Care Support Position
6. Clinical Laboratory Position
7. Radiology Technician
8. Electronics Technician

EXPOSURE CONTROL PROCEDURES

STANDARD PRECAUTIONS: GENERAL PRINCIPLES

1. a. All employees should routinely use appropriate barrier precaution to prevent skin and mucous membrane exposure when contact with blood or other body fluids of any subject is anticipated. Gloves shall be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all subjects, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture, other vascular access or invasive procedures. Gloves shall be changed after contact with each subject, and whenever they are damaged. They shall not be washed for reuse. Change gloves between tasks and procedures on the same subject.

b. Masks and protective eye-wear or face shields (or combinations or goggles or glasses with side shields or masks with side shields) shall be worn during procedures that are likely to generate splashes, sprays, splatters or droplets of blood or other body fluids or potentially infectious materials in order to prevent exposure of mucous membranes. These shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

c. All procedures involving blood or other potentially infectious material shall be performed in such a manner as to minimize splashing, splattering, spraying or generation of droplets of these substances. Lab bench shields shall be used when opening and closing blood tubes and other body fluids. In addition, aerocarriers shall be used in all clinical centrifuges to prevent aerosolation.

d. Lab coats shall be worn when handling blood or other body fluids and when engaging in subject care activities. These shall be removed as promptly as possible if soiled and hands washed immediately.
2. Handwashing facilities should be readily accessible whenever feasible and are equipped with appropriate soaps for proper handwashing, or an alternative method (i.e., alcohol scrub) is made available until hands can be washed with soap and water. Hands and other skin surfaces shall be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed. Handwashing also done when touching contaminated items, whether or not gloves are worn.

Note: Handwashing is the single most effective deterrent to the spread of infection.

3. Sharps: All health care workers should take precaution to prevent injuries caused by needles, scalpels and other sharp instruments or devices such as broken glass, during procedures, especially when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures. To prevent needlestick injuries, needles must not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items shall be placed in puncture-resistant containers for disposal. Where available, self-sheathing safety needles should be used. If unavailable, no attempt to recap used needles shall be made.

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4. These red puncture-resistant containers shall be labeled in accordance with this standard and leak proof on the sides and bottom. They should be easily accessible and located as close as is feasible to the area where sharps are used or can be anticipated to be found. They should be maintained upright and replaced routinely and not allowed to overfill.

5. When doing emergency mouth-to-mouth resuscitation; mouthpieces, resuscitation bags, and other ventilation devices are available in all crash carts and at all CPR stations.

not pregnant. However, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.

7. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

8. Food and drink shall not be kept in refrigerators, freezers, shelves, and cabinets or on countertops or benchtops where blood and other potentially infectious materials are present.

9. Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping, and shall be decontaminated as necessary unless decontamination of such equipment is not feasible due to potential damage to equipment. In such case, the contaminated portion of the equipment shall be designated with a readily observable biohazard label warning that the equipment is contaminated. Such equipment shall be handled very carefully so that all potentially effected persons (employees, service staff etc.) must be informed so they may take appropriate precautions.

10. All personal protective equipment shall be removed prior to leaving work and placed in designated areas for storage, washing and decontamination.

In addition to Standard Precautions there are other categories that shall be adhered to when certain communicable diseases are suspected.

Airborne Precautions:

For subjects known or suspected to be infected with microorganisms transmitted by airborne droplet (small particle residue 5um for smaller in size which remain suspended in air).

Use N95 respirator for suspect or known AFB (isolation for TB) or gloves and mask for varicella.

Droplet Precautions are used for subjects known or suspected to be infected with microorganisms transmitted by droplets (large-particle droplets larger than 5um in size that can be generated by the subject during coughing sneezing, talking or by the performance of certain procedures. Mask and eye protection required. Try and maintain spatial separation of at least 3 feet.

Contact Precautions are used for subjects known or suspected to be infected or colonized with epidemiologically important microorganisms that can be transmitted by direct contact with the subject (hand or skin to skin contact that occurs when performing subject care activities that require touching the subject's dry skin) or direct contact with (touching) environmental surfaces or subject care items in environment. Wear gloves and gown. If use of common equipment is necessary, then adequately clean and disinfect each item before use or another subject

STERILIZATION AND DISINFECTION

Standard sterilization and disinfection procedures for subject -care equipment currently recommended by the Quality Assurance, Care and Safety Committee are adequate to sterilize or disinfect instruments, devices, or other items contaminated with blood and other body fluids from persons infected with bloodborne pathogens, including HIV.

Instruments or devices that enter sterile tissue or the vascular system of any subject, shall be sterilized before reuse. Devices or items that contact intact mucous membrane should be sterilized or receive high-level disinfection, a procedure that kills vegetative organisms and viruses, but not necessarily large numbers of bacterial spores. Chemical germicides that are registered with the US EPA as "sterilants" may be used either for sterilization or for high-level disinfection depending on contact time.

Medical devices or instruments that require sterilization or disinfection shall be thoroughly cleaned before being exposed to the germicide, and the manufacturer's instructions for the use of the germicide should be followed. Further, it is important that the manufacturer's specifications for compatibility of the medical device with the commercial germicides be closely followed. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

In addition to commercially available chemical germicides, a solution of sodium hypochlorite (household bleach) prepared weekly,

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is an inexpensive and effective germicide. Concentrations ranging from approximately 500 ppm (1:100 dilution of bleach) are effective depending upon the amount of organic material (e.g., blood, mucus) present on the surface to be cleaned and disinfected. Commercially available chemical germicides may be more compatible with certain medical devices that might be corroded by repeated exposure to sodium hypochlorite.

HOUSEKEEPING

General Principles

The Medical Department and the GCRC shall be maintained in a clean and sanitary condition. Environmental surfaces such as walls, floors, and other surfaces are not associated with the transmission of infections to patients or health care workers, including the spread of bloodborne pathogens. Therefore, extraordinary measures to sterilize or disinfect these surfaces are unnecessary. However, cleaning and removal of dirt should be done first before disinfecting. Cleaning of walls, blinds and curtains are recommended only when they become visibly soiled. Disinfectant fogging is an unsatisfactory method of decontaminating the air and surface and is not recommended.

The actual removal of microorganisms by scrubbing is at least as important as the choice of the disinfectant or detergent. Disinfectant or detergent formulations registered by the EPA and approved by the Quality Assurance, Care and Safety Committee, can be used for cleaning environmental surfaces. The manufacturer's instructions for appropriate use should be followed.

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible.

Broken contaminated glassware shall not be picked up by hand. Mechanical means of cleanup shall be used (brush, dustpan, forceps, tongs, etc.).

Employees should not reach by hand into containers used to store reusable sharps.

Contaminated instruments shall be handled using gloves at all times.

Cleaning and Decontaminating Spills of Blood and Other Body Fluids

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. Work surfaces shall be decontaminated with an appropriate disinfectant, such as a 1:10 household bleach solution after completion of procedures, as soon as feasible after any spill of blood or other potentially infectious materials.

Small blood or body fluid spills (for example one or two drops) can be decontaminated by wiping them up with gauze soaked with 1:10 bleach. Large blood spills of cultured or concentrated infectious agents should be flooded with a liquid germicide detergent before cleaning and then decontaminated with a 1:10 household bleach solution. In subject care areas, visible material should first be removed and then the area should be decontaminated with 1:10 bleach. In both settings, gloves should be worn during the cleaning and decontaminating procedures. Broken glass should be picked up by a mechanical means. Used gloves and materials for wiping spills should be treated as medical waste. For larger emergency spills call the custodians or ext 2222.

Laundry

1. Contaminated laundry shall be handled as little as possible with a minimum of agitation. Soiled laundry that is contaminated with visible blood shall be handled as contaminated. Contaminated laundry shall be bagged or contained at the location where generated **and not sorted or rinsed in the Medical Department or GCRC areas.**
2. Contaminated laundry shall be transported in bags or containers. Wet or leaking laundry shall be contained in leak-proof bags in addition to the above, prior to transport.
3. Gloves and other protective clothing should be used when handling contaminated laundry
4. All Medical Department Laundry is picked up and delivered by an outside contractor, Dept. Guideline, IC-5.0/3, "Laundry".

Infectious Waste

See Dept. Guideline IC-6.2/7, "Handling and Disposable of Regulated Medical Waste".

Labels and Signs

Biohazard signs, which are fluorescent orange or red-orange, shall be affixed to all containers and storage areas where blood or body fluids are stored. Red bags or red containers may be substituted for labels. (Attachment 1)

Precautions for Clinical and Research Laboratories

Blood and other body fluids from **all** subjects should be considered infected. To supplement the Standard Precautions listed

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above, the following precautions are recommended for health care workers in clinical laboratories.

1. All specimens of blood and body fluids should be transported in a manner that will prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and of the laboratory form accompanying each specimen, and to clean the container or to place it in a secondary container. When transporting specimens in buckets, secondary containers shall be used. When transporting specimens between buildings a laboratory designated vehicle shall be used.
2. All persons processing blood and body fluids specimens (e.g., removing tops from vacuum tubes) must wear gloves. Masks and protective eyewear shall be worn if mucous membrane contact with blood or body fluids is anticipated. Gloves shall be changed and hands washed after completion of specimen processing.
3. For routine procedures such as histologic and pathologic studies or microbiologic culturing, a biological safety cabinet is not necessary. However, biological safety cabinets (Class I or II) should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating and vigorous mixing.
4. Mechanical pipetting devices **MUST** be used for manipulating all liquids in the laboratory. **MOUTH PIPETTING SHALL NOT BE DONE FOR ANY PROCEDURE IN THE LABORATORY.**
5. Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendation for preventing injuries with needles outlined above should be followed.
6. Laboratory work surfaces should be decontaminated with a 1:10 bleach solution after a spill of blood or other body fluids and when work activities are completed.
7. Contaminated materials used in laboratory tests should be decontaminated before reprocessing, or be placed in bags and disposed of in accordance with the Medical Department's guidelines for the disposal of infectious medical waste (IC-6.2).
8. Scientific equipment that has been contaminated with blood or other body fluids shall be decontaminated and cleaned before being repaired in the laboratory or transported to the manufacturer.
9. All persons should remove protective clothing before leaving the laboratory and wash their hands after completing laboratory activities.
10. Gloves must be worn by the phlebotomist when it is "reasonably anticipated" that his/her hands will be contaminated with blood. This includes, but is not limited to work:
 - with uncooperative subjects
 - with non-intact skin
 - during training
 - when performing skin punctures
They should also be changed between subjects

Hepatitis B Vaccine and Post Exposure Evaluation

Hepatitis B vaccine and post-exposure evaluation and follow-up for exposure to bloodborne pathogens is available to all full-time and eligible part-time BNL employees, through Brookhaven National Laboratory Occupational Medicine Clinic (OMC). All exposure incidents should be reported to OMC promptly.

Protocols for pre-exposure vaccination and post-exposure follow-up are available in accordance with OMC policy.

TRAINING

All employees with the potential for occupational exposure shall receive training prior to initial assignments, annually thereafter, and at any time there is a modification in tasks, procedures or requirements.

Training of employees shall address:

1. Explanation of the epidemiology and symptoms of bloodborne diseases.
2. The mode of transmission of bloodborne hazards.
3. A copy and explanation of this exposure control plan.
4. Recognizing job related activities, which could result in exposures.
5. An explanation of the uses and limitations of engineering controls, work practices, and personal protective equipment.
6. Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.
7. How to select personal protective equipment.
8. Information on the safety, efficacy, administration and benefits of hepatitis B vaccine and that it is offered to eligible employees at no cost.
9. Information regarding appropriate actions and persons to contact following exposure to bloodborne pathogens.
10. An explanation of procedures to follow, method of reporting, and medical follow-up after an exposure incident.
11. Explanation of signs, labels, and color-coding as required.

Training Program

ESH Services will be responsible for providing training and information to all employees who have the potential for

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1. exposure to bloodborne pathogens by giving the Bloodborne Pathogen Course. This course is currently on the SBMS database.
2. Activities falling under the responsibility of the Training Coordinator include:
 - a. Maintaining an up-to-date list of facility personnel requiring training.
 - b. Periodically reviewing the training programs to include new information.

Training shall be provided as follows:

- a. At the time of initial assignment to tasks where occupational exposure may take place.
- b. An optional challenge exam may be taken annually.
- c. At any time there is a modification in tasks, programs or requirements.

Training Records

Training Records shall be maintained according to ESH Services Standard Operating Procedures.

The only official copy of this file is the one online at the Medical Department website under "Clinical Research Center Policy Manual." Before using a printed copy, verify that it is the most current version by checking the document effective date on the website.

